

§ 184.1625

21 CFR Ch. I (4–1–02 Edition)

§ 184.1625 Potassium citrate.

(a) Potassium citrate ($C_6H_5K_3O_7 \cdot H_2O$, CAS Reg. No. 006100–0905–096) is the potassium salt of citric acid. It is prepared by neutralizing citric acid with potassium hydroxide or potassium carbonate. It occurs as transparent crystals or a white granular powder, is odorless and deliquescent, and contains one mole of water per mole of potassium citrate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d ed. (1981), p. 242, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, and the Center for Food Safety and Applied Nutrition (HFS–200), 5100 Paint Branch Pkwy., College Park, MD 20740, or may be examined at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section, or different from those set forth in part 181 of this chapter, do not exist or have been waived.

[59 FR 63896, Dec. 12, 1994]

§ 184.1631 Potassium hydroxide.

(a) Potassium hydroxide (KOH, CAS Reg. No. 1310–58–3) is also known as caustic potash, potash lye, and potassa. The empirical formula is KOH. It is a white, highly deliquescent caustic solid, which is marketed in several forms, including pellets, flakes, sticks, lumps, and powders. Potassium hydroxide is obtained commercially from the electrolysis of potassium chloride solution in the presence of a porous diaphragm.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available from inspection at the Office of the Federal Register, 800

North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a formulation aid as defined in § 170.3(o)(14) of this chapter; a pH control agent as defined in § 170.3(o)(23) of the chapter; a processing aid as defined in § 170.3(o)(24) of this chapter; and a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52444, Nov. 18, 1983]

§ 184.1634 Potassium iodide.

(a) Potassium iodide (KI, CAS Reg. No. 7681–11–0) is the potassium salt of hydriodic acid. It occurs naturally in sea water and in salt deposits, but can be prepared by reacting hydriodic acid (HI) with potassium bicarbonate ($KHCO_3$).

(b) The ingredient meets the specifications of the “Food Chemicals Codex,” 3d Ed. (1981), pp. 246–247, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(d) The ingredient is used in table salt in accordance with § 184.1(b)(2) of this chapter as a source of dietary iodine at a maximum level of 0.01 percent.

(e) Prior sanctions for this ingredient different from the uses established in

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this section do not exist or have been waived.

[43 FR 11699, Mar. 21, 1978, as amended at 49 FR 5613, Feb. 14, 1984; 61 FR 14247, Apr. 1, 1996]

§ 184.1635 Potassium iodate.

(a) Potassium iodate (KIO_3 , CAS Reg. No. 7758-05-6) does not occur naturally but can be prepared by reacting iodine with potassium hydroxide.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 245-246, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) The ingredient is used as a dough strengthener as defined in § 170.3(o)(6) of this chapter.

(d) The ingredient is used in the manufacture of bread in accordance with § 184.1(b)(2) of this chapter in an amount not to exceed 0.0075 percent based on the weight of the flour.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[43 FR 11699, Mar. 21, 1978, as amended at 49 FR 5613, Feb. 14, 1984]

§ 184.1639 Potassium lactate.

(a) Potassium lactate ($\text{C}_3\text{H}_5\text{O}_3\text{K}$, CAS Reg. No. 996-31-6) is the potassium salt of lactic acid. It is a hygroscopic, white, odorless solid and is prepared commercially by the neutralization of lactic acid with potassium hydroxide.

(b) FDA is developing food-grade specifications for potassium lactate in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. This regulation does not authorize its use in infant foods and infant formulas. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based

upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavor enhancer as defined in § 170.3(o)(11) of this chapter; a flavoring agent or adjuvant as defined in § 170.3(o)(12) of this chapter; a humectant as defined in § 170.3(o)(16) of this chapter; and a pH control agent as defined in § 170.3(o)(23) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[52 FR 10886, Apr. 6, 1987]

§ 184.1643 Potassium sulfate.

(a) Potassium sulfate (K_2SO_4 , CAS Reg. No. 7778-80-5) occurs naturally and consists of colorless or white crystals or crystalline powder having a bitter, saline taste. It is prepared by the neutralization of sulfuric acid with potassium hydroxide or potassium carbonate.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 252, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) The ingredient is used as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice in accordance with § 184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 0.015 percent for nonalcoholic beverages as defined in § 170.3(n)(3) of this chapter.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[45 FR 6086, Jan. 25, 1980, as amended at 49 FR 5613, Feb. 14, 1984]